

History

Putting the Spotlight on Biotech Innovation

In the spring of 2022, Allucent came into being with the merger of several high-performance companies serving the specialized needs of small and mid-sized biotechs. Derived from the Latin verb alluceo, Allucent means to shine a light upon something or to create an opportunity. With a new name and bold branding, Allucent united the company and its employees under one purpose: putting the spotlight on biotech innovators and helping them deliver treatments to patients with unmet needs.

Company Origins

Allucent originated with CATO SMS, itself created by the merger of Cato Research and SMS-oncology in 2019. Cato Research, founded in 1988, was known for its ability to design and execute successful development strategies and guide creative new products through the regulatory process. SMS-oncology, founded in 2007, was a specialty oncology CRO recognized for delivering a complete range of clinical trial services and providing strategic consulting to companies developing anticancer drugs.

Previous acquisitions by CATO SMS included Array Biostatistics, a full-service biostatistical and statistical programming CRO, and Nuventra Pharma Sciences, one of the industry's leading providers of clinical pharmacology science and services. With these acquisitions, CATO SMS expanded its services to offer biostatistical consulting, analysis, programming, and cutting-edge modeling and simulation techniques to inform clinical trial designs and predict trial outcomes. In early 2022, CATO SMS merged with Pharm-Olam, a global clinical research organization delivering clinical trial services to organizations around the world.

A Fully Integrated Global Company

Today, Allucent delivers innovative strategies and robust solutions based on over 30 years of background in <u>regulatory</u> trends, <u>therapeutic</u> <u>experience</u>, and operational expertise. We share small and mid-sized companies' deep commitment to supporting breakthrough science by partnering with them to navigate the complexities of delivering novel treatments to patients.

With offices across North America, Europe, and the Middle East, Allucent has experience conducting trials in more than 60 countries, focusing on some of the most complex development areas including oncology, rare and orphan indications, and cell and gene therapies. Globally, Allucent has worked on more than 700 clinical trials, with <u>oncology</u> representing the majority.

Contact Us

Let us partner with your team on bringing new therapies to light. Get in touch to get started.

CONTACT US

Services

Clinical Trial Operations

Regulatory and Drug Development Consulting

Government and Public Health Services

Biometrics

Clinical Pharmacology Modeling Simulation

Therapeutic Expertise

Oncology and Hematology

Rare Diseases and Orphan Drugs

Infectious Disease and Vaccine

Cell and Gene Therapy

Central Nervous System

Autoimmune and Inflammation

Allergy and Asthma

Company

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News

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European Headquarters

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Clinical Research Associate / Senior Clinical Research Associate (CRA/SCRA -ONCOLOGY)

Allucent · Utah, United States (Remote) Reposted 6 months ago



Full-time · Mid-Senior level



1,001-5,000 employees · Pharmaceutical Manufacturing

See how you compare to 119 applicants. Retry Premium Free



No longer accepting applications

Meet the hiring team



Tiffany W. · 3rd

Talent Acquisition, Specialist at Allucent | We are a global CRO specialized in complex trials in different therapeutic areas, e.g. oncology, rare.



About the job

Pharm-Olam, LLC & CATO-SMS have merged to form ALLUCENT!

We are a mid-size, full-service Contract Research Organization (CRO) and development organization with a massive global reach. Our international resources are dedicated to helping pharmaceutical and biotechnology companies efficiently and expeditiously navigate the regulatory approval process in order to bring new drugs, biologics, and medical devices to the people who need them. We are a company that strives to deliver cost-effective, quick-to-market clinical services in today's emerging marketplace. We have one of the largest global footprints of any CRO today and we are committed to not only maintain our standard, but to continue to strengthen our presence even further. We are a non-laboratory environment with a unique working environment offering a global team culture as well as a competitive salary & benefits package.

Summary of Role:

To ensure that Investigators are conducting clinical trials in accordance with international Regulatory and Ethical guidelines for Good Clinical Practices (GCP) and International Conference on Harmonization (ICH). May be responsible for assisting the RA Department in the preparation, compilation, submission and maintenance of regulatory documentation required by international regulatory agencies for clinical trials and marketing applications.

This is a full-time, direct hire opportunity for an experienced CRA/SCRA residing in the US (Western / Central US preferred). Ideal candidates should have a variety of trial monitoring (field & remote) and full site management experience working with Oncology trials. This position requires flexibility with travel, on average, 70-80% range.

Responsibilities:

- Provide functional assistance to the project team members with administrative, logistical and practical issues, including the tracking, collection, distribution and filing study documentation.
- · Track and supervise collection of ongoing study data for purpose of regular project status reporting as required.
- Assist the Clinical Operations Manager in conducting feasibility assessment for potential studies.
- · Govern minimum quality standards for trial monitoring activities, with respect to documentation, punctuality of reporting, compliance with objectives, and cooperation with other project team members. Ensure adequate tracking is in place for all activities and reports formatted as required for submission within agreed timelines.
- Monitor activities at clinical study sites to assure adherence to GCP, ICH, SOPs, and study protocols.
- · Collect and review regulatory documents as required.
- · Prepare site visit and telephone reports.
- · Responsible for multiple projects and must work both independently and in a team environment.
- May participate in the study development and start-up process including reviewing protocols, drafting of the Monitoring Plan, designing and/or reviewing CRFs, preparing Informed Consent forms, developing study documents, organizing and presenting at investigator meetings, working with management on monitoring strategy, and/or developing project-specific CRA training.
- · Resolve site issues and determine status for IP shipment.
- · Work with Project Manager (PM), Clinical Team Leader (CTL) and/or Lead Clinical Research Associate (LCRA), regulatory team members or Sponsor to secure authorization of regulatory documents and contracts.
- May translate, coordinate translations or review completed translations of critical documents.
- · Participate in feasibility and/or site identification activities.

- Assist the Project Team with the day-to-day management of clinical studies as required.
- Monitoring Visit Report (MVR) review, management, resolution and escalation as required.
- Train, mentor and/or supervise junior staff.
- May be assigned as LCRA to a regional or global study.
- May be assigned as a reviewer of essential documents (GLP) as a 2nd line or Independent Reviewer (IR).
- · Conducts project co-monitoring, assessment visits and team training.
- Site contact for protocol clarifications and subject enrolment if CRA unavailable.
- · Participate in the development of study newsletters communication as required.
- Assist with the development of project-specific training materials for team.
- Liaise with Business Development and make presentations to potential clients as required.
- · May be required to manage the preparation of local clinical trial applications (for regulatory submissions for new drugs, biologics, or devices).
- Other responsibilities as required.

Requirements / Qualifications:

- At least four years clinical monitoring experience and/or relevant clinical trial experience.
- Relevant life science degree / medical / nursing background, or combination of education and experience.
- Skills to mentor and train other CRAs in a positive and effective manner.
- In-depth knowledge of clinical trials and the critical elements for success in clinical trials.
- Strong therapeutic background.
- · Can demonstrate experience and knowledge in the CRO industry that will support POI's management of clinical trials.
- Has shown ability to successfully manage people/project issues.
- Mature management skills demonstrated by calm and thorough review of situations. Proactively identifies and addresses problems. Seeks to understand all
 contributing factors. Proposes, implements, and evaluates appropriate resolutions.
- Demonstrates the ability to define and meet project requirements.
- Can demonstrate flexibility for improvement and creating solutions.
- Proven organizational abilities, and excellent written and oral communication and presentation skills.
- Excellent team player with team building skills.
- Strong customer focus.
- · A thorough knowledge of regulatory submission and reporting requirements and guidelines.
- Excellent understanding of the drug development process.

Additional Information / Company Benefits:

- Comprehensive benefits package
- · Competitive salaries per location
- Departmental Study/Training Budget for furthering professional development
- Flexible Working hours (within reason)
- · Opportunity for fully hybrid working
- Improved work-life balance
- Internal growth opportunities and career progression
- More task variety
- Financially rewarding internal employee referral program
- · Access to online soft-skills and technical training via GoodHabitz and internal platforms

To be considered further, please apply online at www.allucent.com/careers. You can also send your resume along with salary expectations to desiree.futrell@allucent.com for more information.

We provide equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

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Senior Clinical Research Associate, Utah, United States

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About the company



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Allucent is on a mission to help bring new therapies to light by solving the distinct challenges of small and mid-sized biotech companies. The company is purpose-built through the convergence of leading providers to address this unmet need. Today, Allucent is a global provider of comprehensive drug development solutions, including consulting, clinical operations, biometrics and clinical pharmacology across a variety of therapeutic areas. With more than 30 years of experience in over 60 ... show more

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New York, United States (Remote)





Senior Clinical Research Associate

Redbock - an NES Global Talen... California, United States (Remote)



Clinical Research Associate

Life Science People

United States (Remote)

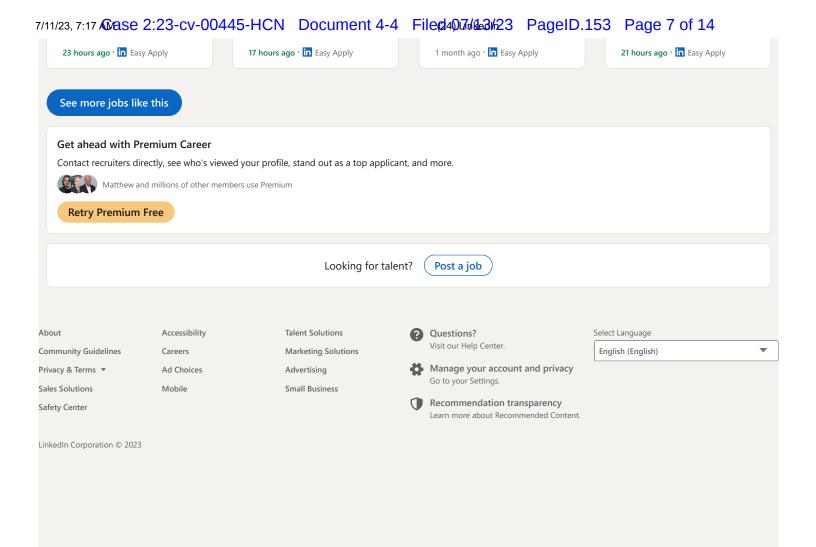




Senior Clinical Research Associate

Elevate Pharma Ltd United States (Remote)





CATO SMS IS NOW ALLUCENT





NEWS PROVIDED BY **Allucent** → 03 May, 2022, 07:00 ET

New Name and Branding Reflect Company's Mission to Help Bring Next-Generation Therapies to Light

News Summary

- Rebranding comes after a series of strategic acquisitions, most recently Pharm-Olam
- · Company's newly combined services address clinical development and consulting needs of small and mid-sized biotechs
- New name unites worldwide experienced workforce in its singular mission

CARY, N.C., May 3, 2022 /PRNewswire/ --

Global biopharmaceutical services leader, CATO SMS, today unveiled its new name, Allucent, with bold branding to emphasize the company's spotlight on serving the specialized needs of small and mid-sized biotech companies.



This move follows a three-year series of strategic acquisitions*, most recently of clinical research provider, Pharm-Olam, that doubled the company's size, strengthened and deepened its capabilities, and expanded its global reach. Now, Allucent is a unified organization with more than 30 years of experience, built to support small and mid-sized biotech companies with achieving breakthrough science.

Currently, smaller companies hold approximately 70% of the biopharmaceutical industry's intellectual property and often benefit from third-party experts possessing clinical and regulatory experience and capabilities to ensure their innovations have the best chance of success. Allucent was formed to address this need, offering full-service clinical trial capabilities, deep therapeutic expertise, product development and consulting services

Mark A. Goldberg, M.D., chairman and chief executive officer, Allucent, said:

"In three short years, we've transformed our company to meet the unique needs of small and mid-sized biotechs. Our new name, Allucent, puts the focus on the clients we exist to serve and aligns our people under our shared passion of helping to bring new therapies to light. As we continue our growth journey, we're committed to making sure we remain big enough to deliver, but small enough to care."

Anchored by deep expertise and a high-touch partnership model, Allucent offers a breadth of specialized services and therapeutic experience geared toward small and mid-sized biotech companies, including:

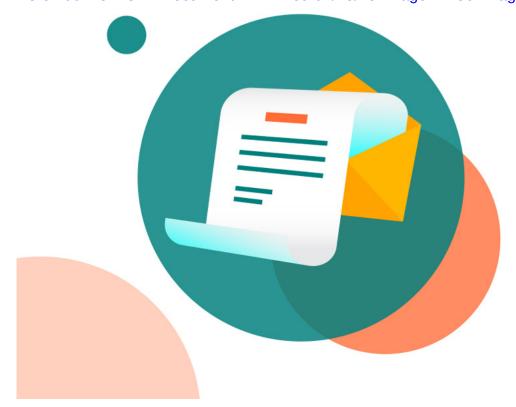
- Flexible clinical and regulatory solutions to successfully navigate the complexities of managing multi-national programs across early and late-stage development, including clinical trial operations; biometrics; decentralized trial capabilities; and clinical pharmacology, modeling and simulation.
- A team of global consultants, focused on strategic product development, regulatory affairs and regulatory submissions with extensive health authority expertise in clinical, non-clinical, CMC and GxP compliance.
- Robust scientific and drug development expertise in key and complex therapeutic areas and modalities with a focus on oncology, cell and gene therapy, rare disease and vaccines.
- A global workforce of 1,200+ employees possessing deep clinical and technical experience with a passion for remaining close to breakthrough science.
- Wide geographic coverage in 60+ countries across North America, Latin America, Europe, India and the Middle East.

*Recent acquisitions include Array Biostatistics in 2020, Nuventra in 2021, and Pharm-Olam in 2022

About Allucent

Allucent is on a mission to help bring new therapies to light by solving the distinct challenges of small and mid-sized biotech companies. The company is purpose-built through the convergence of leading providers to address this unmet need. Today, Allucent is a global provider of comprehensive drug development solutions, including consulting, clinical operations, biometrics and clinical pharmacology across a variety of therapeutic areas. With more than 30 years of experience in over 60 countries, Allucent's individualized partnership approach provides experience-driven insights and expertise to assist its clients in successfully navigating the complexities of delivering novel treatments to patients. Visit Allucent.com for more information.

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Allucent Launches Decentralized Clinical Trial Solution at 2023 World Orphan Drug Congress



NEWS PROVIDED BY **Allucent** → 23 May, 2023, 07:00 ET

Biopharmaceutical Services Provider Allucent Partners with THREAD to Address Modern
Clinical Trial Needs of Small and Emerging Biotech Companies

News Summary

- Global biopharmaceutical services provider Allucent has partnered with THREAD, an
 innovative decentralized clinical trial (DCT) and eCOA technology provider, to launch
 Allucent Patient Direct Trials, a DCT offering focused on small and mid-sized biotech
 companies.
- Allucent Patient Direct Trials provides small and mid-sized biotech companies with access to advanced technologies, operational experience, and regulatory expertise to design and execute more patient-focused trials and realize the efficiencies of a DCT approach.
- The announcement coincides with the 2023 World Orphan Drug Congress, where Allucent will lead a panel session on the value of decentralized study designs and protocol optimization, especially for rare disease therapeutic development.

CARY, N.C., May 23, 2023 /PRNewswire/ -- Global biopharmaceutical services provider

Allucent announced today that it has partnered with THREAD, an innovative DCT and eCOA technology provider, to launch Allucent Patient Direct Trials. The new offering brings advanced

technologies and development and regulatory expertise to small and engine biotechnology companies to support them in designing and overseeing customized decentralized clinical trial approaches that address their needs.

Post-COVID-19, Allucent embraced new digital technologies and enhanced its patient-centric approaches and guidance for optimizing clinical protocols. Allucent Patient Direct Trials leverages this experience to address the needs of many small and emerging biotech companies that may not have the in-house resources required to design and oversee DCTs. Working with THREAD, Allucent's team of regulatory and product development consultants can guide sponsors in determining the most effective and efficient digital strategies for remote engagement and data collection for their studies.

Mark A. Goldberg, MD, chairman and chief executive officer of Allucent, stated, "Allucent Patient Direct Trials enables a highly customized, decentralized clinical trial offering that's laser-focused on meeting the current needs of small and emerging biotech companies. With this launch, we're helping our clients harness new insights and technologies to be more patient-centric and realize the potential and efficiencies of decentralized approaches to clinical research."

Global pharmaceutical and research organizations have increasingly adopted DCTs to make patient participation more accessible and manageable. Leveraging technology, DCTs can expedite recruiting, help retain participants, and increase the diversity of the overall participant pool so trial results are more representative of real-world effectiveness.

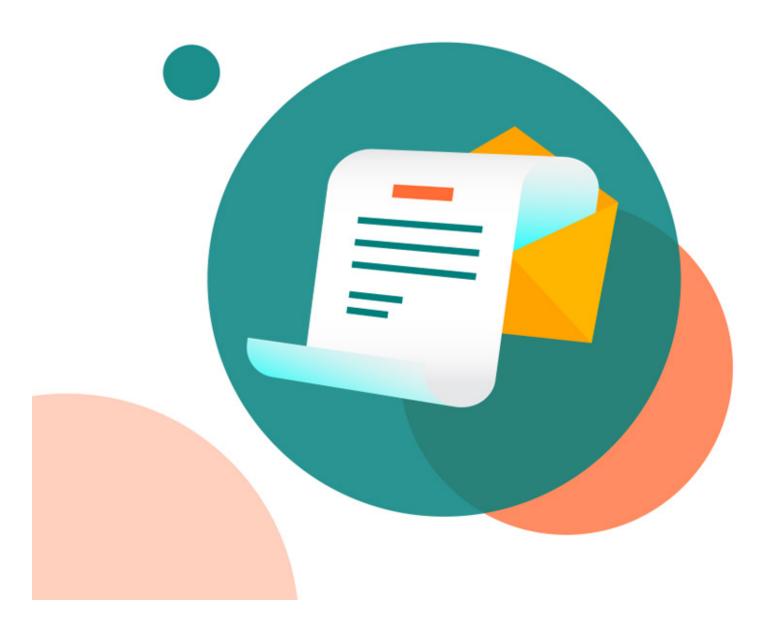
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